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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,670	03/28/2000	FREDERIC BONTE	00060	7942

23338 7590 08/13/2002  
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/13/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/508,670

Applicant(s)

BONTE ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/24/2001, 5/24/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-39 and 42-70 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 and 42-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25, 35-39 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-34 and 42-69 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on September 24, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/508,670 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's arguments submitted on March 24, 2001 are moot, as they were directed to the non-elected species.

### ***Election/Restrictions***

Applicant's election of species set forth in Paper No. 12, filed on May 24, 2002 has been acknowledged. Accordingly, the search is directed to such species encompassing methods of improving cohesion between dermis and epidermis, comprising delivering to skin or hair a person in need thereof, a cosmetically effective amount of ellagic acid, a retinoid, and *pygeum africanum*. Claims 17-25, 35-39, 70 are directed to the elected species and are thus under consideration. Accordingly at this point, claims 26-34, 42-69 are withdrawn from further consideration, because they are not directed to the elected species.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-25, 35-39, 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the disclosure lacks sufficient written description for claimed methods of improving dermis-epidermis cohesion comprising administering ellagic acid to a subject in need thereof.

The first paragraph of 25 USC 112 requires that the "specification shall contain a written description of the invention." This requirement is separate and distinct from the enablement requirement. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). Accordingly, "the essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." In re Barker, 559 F.2d 588, 592n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). The instant application fails to meet such requirements.

First, the only mention of improving the cohesion between dermis and the epidermis, using ellagic acid, is in page 3, lines 20-21 of the specification. There is no other reference in the specification setting forth the details pertaining to such methods to the extent clarifying, how the cohesiveness of the dermis-epidermis junction has improved, what is the improvement relative to, and what process do Applicants have in possession at the time of filing.

Second, the state of art concerning the cohesion between dermis and epidermis is not well established. There is no certainty whether cohesiveness of dermis and epidermis is a function of skin ageing or lack of collagen VII in all possible subjects encompassed by the instant claims. In fact, it is noted that the instant examples are neither exhaustive, nor do they define the claimed methods. There is no working

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example directing one of ordinary skill in the art to methods of improving the cohesiveness of the dermis and epidermis using ellagic acid, retinoids and *pygeum africanum*. Thus, there is no correlation between the exemplified demonstration of the activity of ellagic acid in increasing the proportion of collagen VII in a culture cell and the cohesion between dermis and epidermis layer using the claimed species.

Subsequently, one skilled in the art cannot reasonably conclude that the applicants had possession of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-24, 35-36, 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Arima et al US Patent 5,073,545 ("Arima") (PTO-892, Paper No. 5).

Arima discloses preparations for external application containing ellagic acid in an amount of about 0.001% to 20%, an amino acid and other suitable topical excipients including magnesium oxide, citric acid, vitamins such as vitamin E or A (see abstract, claims 1-9; col 11-12; col 5, lines 1-10). Thus, Arima meets the limitations of the compositions used for the instant cosmetic care methods.

In process claims, a recitation of the intended use does not impart patentability if the intended use does not result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Arima discloses topical administration of his compositions, Arima's

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patent inherently anticipates the limitations of the instant claims, because it meets all the manipulative steps of the claimed methods.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-25, 35-39, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima, in view of Soler et al US Patent 6,113,926 ("Soler") (PTO-892, Paper No. 5) and Seguin et al US Patent 4,549,990 ("Seguin") (PTO-892, Paper No. 5).

Arima's teachings are discussed above. Arima further indicates that various suitable ingredients such as vitamin A (a retinoid) and a suitable plant powder or extract may be added to their compositions for their desired therapeutic effects (see col 5, lines 1-5 and 60-65; col 6, lines 1-11). Arima fails to employ extracts of *pygeum africanum*.

Solar teaches the use of African plums, *pygeum africanum*, in topical cosmetic and pharmaceutical compositions combined with various topical excipients, vitamins, and active agents (see abstract, col 3-4, col 6, lines 40-66). Solar indicates the use of African plums for various utilities including skin care associated with aging or acne (see col 1, lines 5-19; col 6, lines 21-42). Solar does not teach the combination of ellagic acid and *pygenum africanum*.

Seguin is solely use to show that African plum otherwise known as *pygenum africanum*, are readily prepared in powder and extract forms in combination with other vitamins or excipients in the area of cosmetic and pharmaceutical preparations. (see abstract; col 3, lines 55-59; col 4, lines 30-69).

Accordingly, absence of showing unexpected results, it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose;

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idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069(CCPA) 1980. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add *pygeum africanum* extract of Soler to the external compositions of Arima, because as suggested by Arima itself and taught by Soler and Seguin, the ordinary artisan would have reasonably expected to improve the therapeutic benefits of Arima's compositions by adding a suitable herbal extract such as *pygeum africanum*.

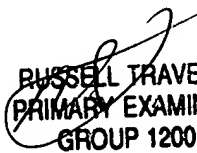
### **Conclusion**

No claims are allowed. Applicant is requested to provide a copy of all pending claims in reply to this Office Action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss  
August 11, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200